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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,489	04/30/2001	David Bach	20816/2	2352

7590
Clifford H. Kraft
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04/19/2005

EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,489

Applicant(s)

BACH ET AL.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-89, 95-101 is/are rejected.
- 7) ☒ Claim(s) 90-94 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed on 1/31/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-81 are cancelled.
2. Claim 82-101 are added to the instant application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claim 101 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 101, the location of the "intermediate separate cladding layer" is confusing. Applicant recites that this intermediate cladding layer is located "between said polymer waveguide core and said waveguide cladding layer, said separate cladding layer passing said detectable light to a detector". It is not clear this intermediate cladding would actually pass detectable light because now there is an extra layer in between the nanowell and the waveguide, whereas the original structure the nanowell is in physical contact with the waveguide layer.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 82-83, 95-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgenson et al. (US 5835645) in view of Delmarche et al. (Science 1997 Vol. 276: 779).

Jorgenson et al. teach a fiber optical sensor for detection of target molecules in a sample. The sensor taught by Jorgenson comprises of a polymer core waveguide and a polymer cladding layer wherein the cladding layer can be removed a portion becoming a sensing area, e.g. nanowell, in contact with the core waveguide layer for detecting sample (See Figure 2 and Figure 3; Col. 3, line 8-22; Col. 6, line 45-55). Jorgenson et al. also teach using a fluidic channel in a separate non-waveguide layer outside the polymer cladding layer, said fluidic channel coupled to an inlet and outlet for conveying sample (See Figure 11). The device also includes a light source optically coupled to the core layer where the light source creating an evanescent wave for detection of analyte (Col. 7, line 25-35). However, Jorgenson et al. do not explicitly teach (1) using plurality of

nanowells in the cladding layers, (2) using plurality of micro-fluidic channels in communication with the nanowells for conveying samples.

Delamarche et al. teach a microfluidic network device comprising plurality of micro-fluidic channels conveying samples to plurality of waveguides (See page 779, Introduction; Figure 1A and 1C). The microfluidic channels are separate from the waveguides, e.g. filling pad and flow-promoting pad (See Figure B and C). The device provides advantages of time-saving, cost-effective and efficiency-increasing for analysis of multiple samples at the same time (Figure 1A and 1C). Additionally, the device taught by Delamarche et al. also can convey fluorescently tagged IgG binding partners into plurality of nanowells for analysis (page 780, right column, first paragraph). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Jorgenson et al. with the plurality of microfluidic channels and fluorescent tagged binding partners as taught by Delamarche et al. for large-scale tests in a plurality of samples in nanowell for efficiency, economy and reproducibility analysis.

With respect to claim 83 and 96, Jorgenson et al. also teach adding capturing molecules, including antigen or antibody bound to the sensing area for detection of binding pair molecules (Col. 8, line 35-42).

4. Claims 84-87, 97-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgenson et al in view of Delmarche et al. as applied to claims 82-83, 95-96 above, and further in view of Fukushima et al. (US 5113470).

Both Jorgenson and Delmarche et al. references have been discussed but do not specifically teach the structure of waveguide or cladding layer as a sheet or film strips for detection purposes. Fukushima et al. teach an optical waveguide device comprising a plurality of optical waveguides with cladding layers extending adjacent each other in a sheet-like form (See Abstract; Figure 1 and 2). Fukushima et al. teach that the sheet-like film structure of the core-waveguide and cladding layer provides advantages of high

Art Unit: 1641

image resolution, high transmission efficiency, low manufacturing cost and minimizing crosstalk among waveguides (Col. 2, line 6-25; Col. 3, line 20-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided both Jorgenson and Delmarche et al. with the sheet-like structures of waveguides and cladding layers as taught by Fukushima et al. since it is known in the analogous art to increase image resolution, high transmission and minimize crosstalk among core-waveguide for low cost.

With respect to claims 86, and 99, applicant recites that the width of the film is 8 mm, 16mm or 32 mm. The teachings of Fukushima et al. provide for the advantages of high detection efficiency and low-cost except for specifying the ranges of the width of the film structure. Therefore, it would have been obvious to one having ordinary skilled in the art at the time the invention was made to vary the waveguide/cladding layer size to optimize detection condition since it has been held discovering the optimum or workable ranges involving only routine skilled in the art. In re Aller, 105 UPSQ 233.

Response to Applicant's Arguments

5. Applicant argues that the newly amended feature “a fluidic layer above or below (separate) a waveguide layer communication with the nanowell to convey the test samples” would over the 103 (a) rejections under Jorgenson et al. in view of Delmarche et al. Applicant's argument has been considered but is not persuasive. As indicated in this Office Action, this separate fluidic channel is taught in Delmarche et al. reference. The microfluidic channels are separate conveying fluid samples from flow-promoting pad to filling pad (See Figure B and C). Therefore, the obviousness rejections under 35 USC §103 (a) are maintained.

Allowable Subject Matter

6. Claims 90-94 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

7. The following is an examiner's statement of reasons for allowance: no prior art fairly suggests or teaches a biosensor with structure of combination with an outer top layer containing at least one port, a fluidic layer having at least one fluidic channel below said top outer layer where a first cladding layer containing at least one micro-cuvette in fluid communication with the fluidic channel, and a core waveguide in contact with the micro-cuvette and a second cladding layer in contact with the core waveguide. The closest prior art is Jorgenson et al., (US 5835645), however, Jorgenson et al. do not contain the structure of placing the cladding (1)-waveguide-cladding layers (2) below a fluidic layer where the first cladding layer having micro-cuvette in fluid communication with the fluidic channel.

Conclusion

8. No claim is allowed.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

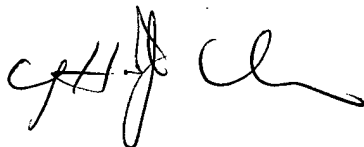
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu

Examiner

Art Unit 1641



April 15, 2005



LONG V. LE
SUPERVISORY PATENT EXAMINER
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04/16/05